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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/254,310 12/06/99 BLANKENSTEIN

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EXAMINER

HM22/0201

MERCHANT GOULD SMITH & EDELL
WELTER & SCHMIDT
3100 NORWEST CENTER
90 SOUTH SEVENTH STREET
MINNEAPOLIS MN 55402-4131

PHAM, M

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

02/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/254,310

Applicant(s)

BLANKENSTEIN, GERT

Examiner

Minh-Quan K. Pham

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 34-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 264.

- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

The amendment filed December 4, 2000, has been entered as Paper No. 11.

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 11 is acknowledged. The traversal is on the ground(s) that claims 34-39 are dependent upon claim 1, and therefore should not be restricted. This is not found persuasive, because even though claims 34-39 are dependent on claim 1, Groups I and II are still distinct inventions as stated in the previous Office action. The requirement is still deemed proper and is therefore made FINAL.

Claims 34-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the other end" in line 6. There is insufficient antecedent basis for this limitation in the claim.

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Claim 1 recites the limitation "the time" in lines 8-9. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the direction" in line 12. There is insufficient antecedent basis for this limitation in the claim.

Claim 2 is vague and indefinite, because it is not clear if the limitation "a longitudinal axis" in line 3 is the same as that recited in line 10 of claim 1, on which claim 2 depends.

Claim 6 recites the limitation "the field generating means" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "the Reynolds number" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "the range" in line 2. There is insufficient antecedent basis for this limitation in the claim.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481

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(Bd. App. 1949). In the present instance, claim 7 recites the broad recitation "in the range of 0.01-500", and the claim also recites "preferably in the range of 0.05-50, in particular in the range of 0.1-25" which is the narrower statement of the range/limitation.

Claim 8 recites the limitation "the lowest" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 8 recites the limitation "the range" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "the field generating means" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "the field generating means" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the field generating means" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "the strength" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "the time" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 17 and 18 recite the limitation "the path" in lines 2 of each claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "the width" in line 1. There is insufficient antecedent basis for this limitation in the claim.

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Claim 19 recites the limitation "the position" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "the volumetric ratio" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "the fluid flow rate" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "the flow rate of the guiding buffers" in line 3. There is insufficient antecedent basis for this limitation in the claim.

The recitation of "and/or" in claim 24 is vague and indefinite, because it is not clear what is included or excluded in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jett et al. (1990), in *Flow Cytometry and Sorting* (eds. Melamed et al.), New York: Wiley-Liss, pages 381-396, in view of either Wada et al. (US 5,465,849, a reference of record) or Hartig et al. (1992), *Electrophoresis*, 13:674-676.

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The claims are drawn to an capillary apparatus for cell sorting, such as flow cytometry , and cell separation due to their susceptibility to a field.

Jett et al. disclose apparatuses for flow cytometry and methods for detection, including the use of immunoassays (see whole document, especially pages 388-393, Amplified Flow Cytometric Fluoroimmunoassays).

Jett et al.; however, differ from the claimed invention because they do not disclose the separation of particles using a magnetic field.

Wada et al. disclose the separation of particles in accordance with their magnetic susceptibility (see column 1, line 50 to column 2, line 63).

Hartig et al. disclose the separation of magnetically labelled biological particles by application of a magnetic field perpendicular to the direction of flow (see abstract; and page 676, last paragraph).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the magnetic separation apparatus of Wada et al. in the apparatus of Jett et al., because the separation apparatus of Wada et al. has the advantage of being able to separate small particles (see Wada et al.: column 1, lines 51-55).

Claims 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. (US 5,304,487).

Wilding et al. disclose a device for analysis comprising microchannels with immobilized binding moieties in a detection region (see column 2, line 40 to column 5, line 5; and column 7,

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lines 1-12). The device may have multiple fluid handling regions for analysis of different analytes (see figure 1; and column 7, lines 29-39).

Wilding et al. differ from the claimed invention because they do disclose multiple detection regions in the device.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use multiple detection regions in the device of Wilding et al. in order to detect multiple analytes in a single pass. The multiple detection region configuration would have been obvious because it is merely a duplication of parts of the device of Wilding et al., and thus, has no patentable significance (see MPEP 2144.04).

Allowable Subject Matter

Claim 32 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: Although the prior art disclose apparatus for analysis comprising microchannels with immobilized reagents, there is no motivation or suggestion to immobilize the reactants in the microchannel using an electric field. Therefore, claim 32 is allowable over the prior art.

Conclusion

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ulnert (US 5,674,743); Moore (1998), *Journal of Biochemical and Biophysical Methods*, 37:11-33; Hodder et al. (1997), *Analyst*, 122:883-887; Sun et al., *Cytometry*, 33:469-475; Zborowski et al. (1996), *ASAIO Journal*, 42(5):M666-671; and Blankenstein et al. (1998), *Biosensors and Bioelectronics*, 13(3-4):427-438, are cited to show particle separation using electric or magnetic fields.

Ryan (US 5,460,797 and US 5,811,099); Kachel et al. (1990), in *Flow Cytometry and Sorting* (eds. Melamed et al.), New York: Wiley-Liss, pages 27-44; and Lea et al. (1990), in *Flow Cytometry and Sorting* (eds. Melamed et al.), New York: Wiley-Liss, pages 367-380 are cited to show details and methods of flow cytometry.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Quan K. Pham, Ph.D., whose telephone number is (703) 305-1444. The examiner can normally be reached on Monday to Friday, 8 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Minh-Quan K. Pham, Ph.D.

January 8, 2001

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641